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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,539	10/04/1999	LOUIS S. KUCERA	0044317U3	9782
28977	7590	09/22/2005	EXAMINER	
MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.	Applicant(s)	
09/412,539	KUCERA ET AL.	
Examiner	Art Unit	
Brenda L. Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 56,69-71,107 and 110-112 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56,69-71,107 and 110-112 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 56, 69-71, 107 and 110-112 are pending in the application.

This action is in response to applicants' amendment filed March 22, 2004. Claim 107 has been amended.

### ***Response to Amendment***

Applicants' arguments filed March 22, 2004 have been fully considered with the following effect:

1. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 101, rejection of claims 56, 69-71, 107 and 110-112, labeled paragraph 3 in the last office action, which is hereby **withdrawn**.
2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 56, 69-71, 107 and 110-112, labeled paragraph 3 in the last office action, which is hereby **withdrawn**.

In view of the amendment dated March 22, 2004, the following new grounds of rejection apply:

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 107 and 110-112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

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- a) Claims 107 and 110-112 are vague and indefinite in that it is not known what is meant by the nomenclature of the species, which is missing the point of attachment of the dodecyloxy.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 56, 69-71 and 107 and 110-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piantadosi et al., WO 91/19726. The generic structure of Piantadosi encompasses the instantly claimed compounds (see Formula (I) on page 3) and for the same uses as claimed herein. The examples as set forth in claims 15-20 differ only in the nature of the substituents  $W_1$ ,  $W_2$ ,  $R_1$ ,  $R_2$ ,  $X_1$ ,  $n$ ,  $X_2$ ,  $Y$ ,  $Z$  and  $B$ . Page 2, line 32 through page 3, line 17 defines the substituents  $W_1$ ,  $W_2$ ,  $R_1$ ,  $R_2$ ,  $X_1$ ,  $n$ ,  $X_2$ ,  $Y$ ,  $Z$  and  $B$  as follows:  $W_1$  is S, O, **NHC(=O)**, or NH;  $W_2$  is S, O, **NHC(=O)**, **OC(=O)**, NH, or a covalent bond;  $R_1$  is C10-C20 saturated or unsaturated alkyl;  $R_2$  is H or C1-C20 saturated or unsaturated alkyl;  $X_1$  and  $X_2$  are each independently **oxygen** or a covalent bond;  $n$  is zero or one;  $Y$  is H, F or **N<sub>3</sub>**;  $Z$  is **H** or F; and  $B$  is adenine, **thymine**, cytosine, etc. The compounds of the instant invention are generically embraced by Piantadosi in view of the interchangeability of the substitutions of the phospholipid. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated

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to select for example  $W_1$  is NHC);  $W_2$  is O;  $R_1$  is  $C_{11}H_{23}$  or  $C_{12}H_{25}$ ;  $R_2$  is  $C_{10}H_{21}$ ;  $X_1$  is O;  $n$  is 0;  $X_2$  is O;  $Y$  is  $N_3$ ;  $Z$  is H; and  $B$  is thymine as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).


Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 56, 70, 107 and 111 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8, 9, 33-36 and 41-43 of U.S. Patent No. 6,030,960. Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. '960 embraces the method of use of the compounds of claims 56 and 107, where  $Y$  is O or  $NHCO$ ;  $R_1$  is  $C_{11}H_{23}$  or  $C_{12}H_{25}$ ;  $X$  is a methylene substituted by  $H_{21}C_{10}O-$ ;  $D$  is formula V where  $E$  is formula VII.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Brenda L. Coleman  
Primary Examiner Art Unit 1624  
September 19, 2005